

REMARKS/ARGUMENTS

Reconsideration and the withdrawal of all outstanding rejections are hereby respectfully requested in view of the above amendments and the following remarks:

- 1) Applicant notes the Examiner has imposed a restriction requirement regarding claims 46 – 49 and that the Examiner has withdrawn claims 46 – 49 from consideration as being directed to a non-elected invention.
- 2) Claim 41 is rejected under 35 U.S.C. §112, second paragraph, as being indefinite for using the term “substantially” and for reciting that the adhesive layer contains a “pigment for imparting a discernable color to the first layer of the wound dressing,” which the Examiner states is vague and indefinite as being unclear how the adhesive layer comprising a pigment would impart a color to another separate layer. Further, the Examiner states that it is unclear how the first layer can be “substantially transparent” and have a discernable color that is imparted by the pigment of the adhesive layer.

Applicant’s claim 41 has been amended to state that adhesive layer contains “a pigment from imparting a discernable color to the adhesive layer that may be seen through the first layer of the wound dressing.” Since the first layer of the wound dressing is substantially transparent and the second layer of the wound dressing is substantially opaque, the discernable color imparted by the pigment to the adhesive layer may only be seen through the substantially transparent layer and not the substantially opaque layer. Accordingly, the discernable color creates a visual indicator for differentiating one side of the dressing from the other side of the dressing in the field, since the discernable color may be seen from one side of the invention through the substantially transparent layer and not seen from the other side of the dressing

because the view of the discernable color from the other side of the dressing is blocked by the substantially opaque layer.

Regarding the term “substantially,” reconsideration is respectfully requested since the MPEP at §2173.05(b)(D) (copy enclosed) indicates that the term is not indefinite. One of ordinary skill in the art would know what was meant by “substantially transparent”, and for that matter “substantially opaque.” So long as the first layer of the dressing is at least transparent enough so that the color of the pigment in the adhesive layer may be seen through the first layer of the dressing, and the second layer of the dressing is opaque enough so that the color in the adhesive layer may not be seen through the second layer of the dressing, a visual indicator is created for differentiating one side of the dressing from the other side in the field.

3) Claims 34 – 37 and 44 – 45 are rejected under 35 U.S.C. §102(e) as being anticipated by Lindqvist (6,051,747). Applicant respectfully traverses this rejection.

As recited in Applicant’s claim 34, Applicant’s dual-purpose wound dressing comprises a multi-layered composite structure that has a **first wound contacting side** having an outer wound contacting surface that has wound healing characteristics and a **second wound contacting side** having an outer wound contacting surface that has wound healing characteristics different from the wound healing characteristics of the outer surface of the first side of the composite structure. Further, Applicant’s claim 34 recites that the multi-layered structure includes a first layer forming the **first wound contacting side** of the composite structure, the first layer being a **membrane layer**, and a **second layer** forming the second wound contacting side of the composite structure, the second layer being a foam layer. This is not taught or disclosed or suggested by Lindqvist.

Contrary to the Examiner’s contention, Lindqvist is structurally distinguishable from the

Applicant's claimed invention. Unlike Applicant's claimed invention which has (1) a membrane layer as a first wound contacting side having an outer wound contacting surface and (2) a foam layer as a second wound contacting side having an outer wound contacting surface, Lindqvist does not have a foam layer as a second wound contacting side having an outer wound contacting surface. Although Lindqvist has an absorbent foam layer 2, Lindqvist's foam layer 2 does not come into direct contact with a patient's wound since it is sandwiched between two other layers in the Lindqvist wound dressing shown in Fig. 1 of Lindqvist. Specifically, Lindqvist's foam layer 2 is provided with a gel layer on one side and a liquid-impervious layer 5 on the other side. Moreover, Lindqvist actually teaches away from Applicant's invention. For example, Lindqvist states at column 2, lines 54 -56, that "The gel layer also forms a spacing layer which prevents the foam material from coming into direct contact with the wound or skin of the wearer." (emphasis added) The embodiment of Linqvist's invention shown in his Fig. 2 also fails to disclose a wound dressing having a foam layer as a second wound contacting side having an outer wound contacting surface, as is recited in Applicant's claim 34. The outer surface of Lindqvist's foam layer is not a wound contacting surface. Rather, the outer surface of Lindqvist's foam layer may be used to have a further absorbent body loosely applied to it so that the "additional absorbent body can then be easily removed, without needing to remove the dressing" (Lindqvist at Col. 4, lines 50 – 55). The outer surface of Lindqvist's foam layer may also be provided with a liquid-impervious layer. (Lindqvist at Col. 4, lines 56 – 58).

Accordingly, withdrawal of the rejection of claim 34 is respectfully solicited.

Applicant's claims 35 – 37 and 44 – 45 depend from Applicant's claim 34 and are patentable for the same reason. Further, these claims add additional claim elements which further define Applicant's invention over the cited reference.

(4) Claims 34, 36, 40, and 45 are rejected under 35 U.S.C. §102(b) as being anticipated by Hofeditz (4,552,138). Applicant respectfully traverses this rejection.

Unlike Applicant's invention recited in Applicant's claim 34, Hofeditz does not disclose a dual purpose wound dressing having **both** a membrane layer as a **first wound contacting side** having an outer wound contacting surface that has wound healing characteristics and a **second wound contacting side** having an outer wound contacting surface that has wound healing characteristics different from the wound healing characteristics of the outer surface of the first side.

While Hofeditz has a gel layer having an outer wound contacting surface, Hofeditz, in contrast to Applicant's invention, has a foam layer as an intermediate or cover layer. Hofeditz does not disclose a foam layer having an outer wound contacting surface having wound healing characteristics, as called for by Applicant's claim 34.

Accordingly, withdrawal of the rejection of claim 34 is respectfully requested.

Applicant's claims 36, 40, and 45 depend from Applicant's claim 34 and are patentable for the same reason. Further, these claims add additional claim elements which further define Applicant's invention over the cited reference.

5) Claims 34 – 36, 38, 42 – 43, and 45 are rejected under 35 U.S.C. §102(b) as being anticipated by Freeman (5,681,579). Applicant respectfully traverses this rejection.

In contrast to Applicant's invention recited in Applicant's claim 34, Freeman, does not disclose a dual-purpose wound dressing having **both** a membrane layer as a **first wound contacting side** having an outer wound contacting surface that has wound healing characteristics and a **second wound contacting side** having an outer wound contacting surface that has wound healing characteristics different from the wound healing characteristics of the outer surface of the

first side. Freeman discloses a various wound dressings comprising a polymeric support layer and an occlusive backing layer overlaying the support layer. Typically, an adhesive layer is applied to the outer face of the support layer, or to the inner surface of an overhanging portion of the occlusive backing layer, for adhering the dressing to the skin of a patient. Freeman's occlusive backing layer does not have an outer wound contacting surface having wound healing characteristics, as called for in Applicant's claim 34.

Accordingly, withdrawal of the rejection of claim 34 is respectfully solicited.

Applicant's claims 35, 36, 38, 42 -43, and 45 depend from Applicant's claim 34 and are patentable for the same reason. Further, these claims add additional claim elements which further define Applicant's invention over the cited reference.

6) Claims 39 – 41 are rejected under 35 U.S.C. §103(a) as being unpatentable over Lindqvist (6,015,747) in view of Lorenz (5,258,421), claim 42 is rejected under 35 U.S.C. §103 (a) as being unpatentable over Lindqvist (6,015,747) in view of Lorenz (5,258,421) and in further view of Cartmell (5,160,328), and claims 37, and 39 -41 are rejected under 35 U.S.C. §103(a) as being unpatentable over Freeman (5,681,579) in view of Lorenz (5,258,421). Applicant respectfully traverses these rejections.

None of the cited references teaches or suggests, either alone or in combination, Applicant's dual-purpose wound dressing having a **first wound contacting side** having an outer wound contacting surface that has wound healing characteristics and a **second wound contacting side** having an outer wound contacting surface that has wound healing characteristics different from the wound healing characteristics of the outer surface of the first side of the composite structure.

Regarding the §103(a) rejection based on the combination of Lindqvist in view of Lorenz,

neither Lindqvist nor Lorenz discloses a wound dressing having a first wound contacting side having an outer wound contacting surface having wound healing characteristics and a second wound contacting side having an outer wound contacting surface that has wound healing characteristics different from the wound healing characteristics of the outer surface of the first side. There is no suggestion to be gleaned from either reference to produce a wound dressing that has **both** a first wound contacting side having an outer wound contacting surface that has wound healing characteristics and a second wound contacting side having an outer wound contacting surface that has wound healing characteristics different from a wound healing characteristics of the outer surface of the first side. Both Lindqvist and Lorenz show dressings having only one outer wound contacting surface for contacting a wound, and there is no suggestion in these references to use the dressings of the references as intended and also in an "up-side down" orientation, if desired, so as to provide a choice of wound healing characteristics from one dressing to a wound.

As pointed out above, Lindqvist discloses a dressing that has only one outer wound contacting surface. Lorenz also has only one outer wound contacting surface, with only the gel layer of the dressing being applied to the patient's wound. In Lorenz, the substrate layer merely provides reinforcement, a gas and liquid barrier, a support with gas and liquid permeability, and/or protection for the gel and the area of treatment, etc. In Lorenz, if the tacky gel layer is not applied to the entire substrate layer, the non-gel coated inner surface of the substrate layer may be provided with an additional adhesive which contacts the intact skin while the absorbent adhesive gel layer contacts the wound. Accordingly, there is nothing in the references, either taken alone or in combination, that suggests a wound dressing having two different outer wound contacting surfaces having two different wound healing characteristics.

Regarding the combination of Lindqvist in view of Lorenz and further in view of Cartmell, none of these references, either alone or in combination, teaches or suggests Applicant's claimed "two-sided" wound dressing. The suggestion drawn from Lindqvist and Lorenz, as set out above, is a "single-sided" bandage. The teachings of Cartmell do not add anything to the suggestion drawn from Lindqvist and Lorenz. Specifically, Cartmell discloses a self-adhesive bandage that only has one outer wound contacting surface. Accordingly, there is no suggestion in these references, again either taken alone or in combination, to produce a "two-sided" dressing.

Regarding the combination of Freeman in view of Lorenz, the suggestion to be drawn from these references, either taken alone or in combination, is the production of a "single-sided" dressing. Both of these references show an adhesive layer being provided to the dressing so that it may only be used in one orientation, adhesive side down.

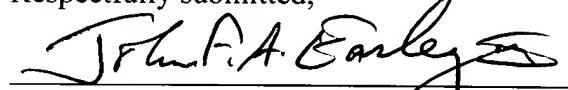
With respect to each of the §103(a) rejections, the combination of the references fails to show any suggestion for producing a "two-sided" dressing since the disclosures of these references only show "single-sided" dressings.

7) Regarding the Examiner's statement that ". . . the instantly claimed aesthetic design change does not impart patentable significance with regard to the mechanism in which the wound article functions" with regard to claim 40, Applicant notes that claim 40 does not merely recite an aesthetic design change. As pointed out above in this amendment, the pigmented adhesive layer provides a visual indicator for differentiating one side of the dressing from the other side of the dressing in the field.

8) New claims 50 - 54 have been added to round out the coverage of the claims.

- 9) If necessary, an appropriate extension of time to respond is respectfully requested.
- 10) The Commissioner is authorized to charge any additional fees which may be required to Patent Office Deposit Account No. 05-0208.

Respectfully submitted,



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B. "Essentially"

The phrase "a silicon dioxide source that is essentially free of alkali metal" was held to be definite because the specification contained guidelines and examples that were considered sufficient to enable a person of ordinary skill in the art to draw a line between unavoidable impurities in starting materials and essential ingredients. *In re Marosi*, 710 F.2d 799, 218 USPQ 289 (CCPA 1983). The court further observed that it would be impractical to require applicants to specify a particular number as a cutoff between their invention and the prior art.

C. "Similar"

The term "similar" in the preamble of a claim that was directed to a nozzle "for high-pressure cleaning units or similar apparatus" was held to be indefinite since it was not clear what applicant intended to cover by the recitation "similar" apparatus. *Ex parte Kristensen*, 10 USPQ2d 1701 (Bd. Pat. App. & Inter. 1989).

A claim in a design patent application which read: "The ornamental design for a feed bunk or similar structure as shown and described." was held to be indefinite because it was unclear from the specification what applicant intended to cover by the recitation of "similar structure." *Ex parte Pappas*, 23 USPQ2d 1636 (Bd. Pat. App. & Inter. 1992).

D. "Substantially"

The term "substantially" is often used in conjunction with another term to describe a particular characteristic of the claimed invention. It is a broad term. *In re Nehrenberg*, 280 F.2d 161, 126 USPQ 383 (CCPA 1960). The court held that the limitation "to substantially increase the efficiency of the compound as a copper extractant" was definite in view of the general guidelines contained in the specification. *In re Mattison*, 509 F.2d 563, 184 USPQ 484 (CCPA 1975). The court held that the limitation "which produces substantially equal E and H plane illumination patterns" was definite because one of ordinary skill in the art would know what was meant by "substantially equal." *Andrew Corp. v. Gabriel Electronics*, 847 F.2d 819, 6 USPQ2d 2010 (Fed. Cir. 1988).

E. "Type"

The addition of the word "type" to an otherwise definite expression (e.g., Friedel-Crafts catalyst) extends the scope of the expression so as to render it indefinite. *Ex parte Copenhaver*, 109 USPQ 118 (Bd. App. 1955). Likewise, the phrase "ZSM-5-type aluminosilicate zeolites" was held to be indefinite because it was unclear what "type" was intended to convey. The interpretation was made more difficult by the fact that the zeolites defined in the dependent claims were not within the genus of the type of zeolites defined in the independent claim. *Ex parte Attig*, 7 USPQ2d 1092 (Bd. Pat. App. & Inter. 1986).

F. Other Terms

The phrases "relatively shallow," "of the order of," "the order of about 5mm," and "substantial portion" were held to be indefinite because the specification lacked some standard for measuring the degree intended and, therefore, properly rejected as indefinite under 35 U.S.C. 112, second paragraph. *Ex parte Oetiker*, 23 USPQ2d 1641 (Bd. Pat. App. & Inter. 1992).

The term "or like material" in the context of the limitation "coke, brick, or like material" was held to render the claim indefinite since it was not clear how the materials other than coke or brick had to resemble the two specified materials to satisfy the limitations of the claim. *Ex parte Caldwell*, 1906 C.D. 58 (Comm'r Pat. 1906).

The terms "comparable" and "superior" were held to be indefinite in the context of a limitation relating the characteristics of the claimed material to other materials - "properties that are superior to those obtained with comparable" prior art materials. *Ex parte Anderson*, 21 USPQ2d 1241 (Bd. Pat. App. & Inter. 1991). It was not clear from the specification which properties had to be compared and how comparable the properties would have to be to determine infringement issues. Further, there was no guidance as to the meaning of the term "superior."

>The phrase "aesthetically pleasing" was held indefinite because the meaning of a term cannot depend on the unrestrained, subjective opinion of the person practicing the invention. *Datamize LLC v. Plumtree Software, Inc.*, 417 F.3d 1342, 1347-48, 75 USPQ2d 1801, 1807 (Fed. Cir. 2005).<